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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,497	05/19/1999	BRIAN E. SCHINDLY	MED-2-1012	5279

7590 05/22/2002

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 05/22/2002

61

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-11

**Office Action Summary**

Application No.

09/314,497

Applicant(s)

SCHINDLY ET AL.

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

### **DETAILED ACTION**

1. This final office action is in response to the amendment received on 02/15/2002.
2. Please refer to the non-final office action (11/06/2001) pages 3-6.

### ***Response to Arguments***

3. Applicant's arguments filed 02/15/2002 have been fully considered but they are not persuasive.

On page 5 of the response, applicant argues that Ignacio provides no motivation to locate monitor remote from the item to be sterilized. However, the claims in the application recite "an indicator on the porous portion" without providing a specific location. In figure 4, of the application, the porous portion can be 72, 98, or 42. If the indicator is put on the surface 72, then it is not remote from the item. Furthermore, with regard to the position of the indicator, it is a routine experimentation to place the indicator close or far from the item to be sterilized. In addition, Ignacio teaches that the indicator can be included in the chamber along with the item to be sterilized (col.9, lines 57-59). Thus, one of ordinary skill in the art would have been motivated when selecting the appropriate place of the indicator to place the indicator on the package or inside the package as taught by Ignacio.

On page 7 of the response, applicant argues that Ignacio monitor does not indicate whether the item to which it is attached has operated properly. Ignacio teaches that the indicator can be placed on the package containing the item (remote from the item), on the item itself, or included within the package (remote from the item) in order

to insure that the item has been sterilized effectively (i.e., proper exposure time, proper exposure temperature, and proper concentration level of the sterilant).

On page 8 of the response, applicant argues that Ignacio does not place a monitor on its sterilant source. The claims in the application do not mention of placing the monitor on the sterilant source. However, Ignacio's indicator insures proper concentration level of the sterilant during the process of sterilization.

### ***Conclusion***

**4. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**5.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MONZER R CHORBAJI** whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

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6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*  
Patent Examiner  
AU 1744  
May 19, 2002

*Robert J. Warden, Sr.*  
ROBERT J. WARDEN, SR.  
SUPERVISORY PATENT EXAMINER  
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